

Delaware Division of Public Health
DECLARATION OF SHORTAGE

NOW COMES, the Division of Public Health, by and through Jaime "Gus" Rivera, MD, FAAP Director, pursuant to 16 Del.C. §510(b), who has determined that a shortage of mercury-free Japanese Encephalitis vaccine (JEV) exists for children under 8 years or pregnant women who are traveling to areas where Japanese Encephalitis is epidemic, and who sets forth this Declaration, and herein states as follows:

RECITALS

WHEREAS, pursuant to 16 Del.C. §122(1) the Department of Health and Social Services has "supervision of all matters relating to the preservation of the life and health of the people of the State;" and

WHEREAS, 16 Del.C. §510 (a) restricts the administration of vaccines containing mercury to children under 8 years or pregnant women; and

WHEREAS, 16 Del.C. §510 (b) (3) states that the prohibition against the use of vaccines containing mercury shall not apply when "the Director of the Division of Public Health or their designee determines that a shortage of the vaccine exists which could threaten the health of groups of individuals within the State including children under eight (8) years of age or pregnant women, and additional mercury-free vaccine cannot be made available from other medical providers, manufacturers, distributors, agencies, jurisdictions or by any other means."

WHEREFORE, the Director of the Division of Public Health determines that:

- (1) There exists a shortage of supply of mercury-free Japanese Encephalitis vaccine that could threaten the health of children under the age of 8 and pregnant women, in the State of Delaware, who are traveling to areas where Japanese Encephalitis is epidemic
- (2) Additional mercury-free Japanese Encephalitis vaccine cannot be made available from other medical providers, manufacturers, distributors, agencies, jurisdictions, or by any other means; and
- (3) The use of mercury containing Japanese Encephalitis vaccine (hereinafter "JEV") is necessary to ensure these groups have access to vaccinations.

IN SUPPORT of this determination, the Director finds as follows;

- 1) The JEV is administered to persons traveling to areas where Japanese Encephalitis is epidemic or endemic;

2) The Director of the Division of Public Health finds that all JEV currently manufactured contains mercury and there are no plans by the manufacturer to change its formulation.

Pursuant to 16 Del. C. §510, a provider administering a mercury containing vaccine pursuant to this determination of shortage shall inform the client, parent or legal guardian of the client that the vaccine contains mercury, that they believe the vaccine to be medically necessary, and that the Director of Public Health has made a formal determination that the vaccine may be administered due to the existence of the shortage of mercury-free vaccines.

This determination of shortage is applicable for 12 months from the date of signature, and may be re-issued or amended upon further determination by the Director. This determination will be rescinded prior to 12 months from the date of signature if the Director determines that an FDA-approved mercury-free vaccine is, or can be made, adequately available.



Jaime "Gus" Rivera, MD, FAAP
Director, Delaware Division of Public Health

10/28/18

Date